REMARKS

A detailed listing is presented, with appropriately defined status identifiers, for all claims that are or were in the application, irrespective of whether the claims remain under examination. This amendment changes claims in this application such that, upon entry of the response, claims 91-128 will be pending.

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are sought to be cancelled by the present amendment without prejudice to or disclaimer of the subject matter therein, so that claims 1-90 stand cancelled.

New claims 91-128 are sought to be added. These new claims correspond roughly to previously pending claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90, with the exception that new claims 91, 111, 115, 116, and 117 have been drafted to clarify Applicants' invention by adding the phrase "into the (or a) urethra" in the context of administering a hydrogel prosthetic device, or injecting a hydrogel or a urethral bulking agent. Support for this addition can be found in the specification as filed, for example, at page 8, lines 30-35.

These changes are believed to introduce no new matter, and their entry is respectfully requested. Applicants also respectfully request reconsideration of the application in view of the foregoing amendments and these remarks.

I. Statement of the Substance of the Interview

In reply to the Interview Summary Form PTOL-413 issued on May 21, 2008, Applicants' undersigned representative provides the following statement of the substance of the telephonic interview held with the Examiner to discuss the captioned application.

Applicants' undersigned representative and Mr. Pierre Kary conducted a telephonic interview with the Examiner on May 16, 2008. During the interview, the state of the art at the time of the invention was discussed, in particular, the use of polyacrylamide for the purposes of the invention. The application was discussed, along with the claimed methodology. It was agreed that Applicants would submit declarations attesting to the state of the art at the time of the invention, and to support of claimed invention. Accordingly, Applicants concurrently submit three Rule 132 declarations by Robert Lessél, Ieva Ankorina-Stark, and David Diamond, respectively.

Applicants wish to thank Examiner Fubara for the courteous and helpful interview held on May 16, 2008.

II. Rejection of the Claims Under 35 U.S.C. § 112

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 82-84 and 86-90 stand rejected as allegedly failing to comply with the written description requirement because, according to the Examiner, claim 9 recites "resistance of passage of urine through the urethra" and the specification as originally filed does not provide support for this limitation. (Office Action, at page 3, line 19, to page 4, line 2, paragraph 3.) The Examiner states that "applicant has not pointed to the section of the specification as originally filed that supports this amendment." (Office Action, at page 3, line 24, to page 4, line 1.)

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 82-84 and 86-90 have been cancelled, rendering moot the rejection.

New independent claim 91, however, is directed to a method of treating urinary incontinence comprising increasing resistance of passage of urine through a urethra, and recites the phrase at issue.

Applicants submit that the phrase "resistance of passage of urine through the urethra" is supported by the specification as originally filed, for example, at page 1, lines 14-20, and at page 2, lines 1-3. Applicants believe that these cited passages would reasonable convey to one of skill in the art that the inventors had possession of the subject matter of new claim 91. The subject matter of a claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. See Manual of Patent Examining Procedure (MPEP), 8th Ed., at § 2163.03, at page 2100-186 (August 2007).

Thus, Applicants submit that one of skill in the art, in light of the cited passages in the specification, would recognize that the inventors, at the time the application was filed, had possession of the invention of new claim 91 and its dependent claims. Accordingly, Applicants believe that the rejection of claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 82-84 and 86-90 under 35 U.S.C. § 112, first paragraph, has been overcome or rendered moot and respectfully request that the Examiner withdraw the rejection.

III. Rejection of the Claims Under 35 U.S.C. § 103

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 stand rejected as allegedly being unpatentable over Pavlyk, U.S. Pat. No. 5,798,096 ("Pavlyk") in view of RU 2148957 ("Sknar") and Applicants' admission (in Applicants' February 23, 2006 interview at the US PTO, and in Applicants' remarks filed on February 27, 2006), and further in view of Annis *et al.*, U.S. Pat. No. 4,857,041 ("Annis"). (Office Action, at page 4, lines 14-17, paragraph 5.) Applicants respectfully traverse this rejection.

Specifically, the Examiner contends that Pavlyk discloses cross-linked polyacrylamide hydrogel(s) meeting the limitations of the acrylamide hydrogels of the claims, and that the hydrogel of Pavlyk would inherently exhibit the intended uses of the claimed hydrogel and would have the claimed properties. (Office Action, at page 5, lines 1-12.) The Examiner also contends that since the reaction between the acrylamide monomer and the methylene bis-acrylamide monomer cross-linking agent goes to completion, and since the residual monomer in the product is expected to be very minimal if any, Pavlyk renders less than 50 ppm monomeric units obvious. (Office Action, at page 5, lines 16-20.) The Examiner further argues that "applicant has not provided factual evidence that the reaction between the acrylamide and the methylene bis-acrylamide does not go [to] completion." (Office Action, at page 8, lines 18-19.)

Applicants submit that, contrary to the Examiner's contention, Pavlyk does not disclose polyacrylamide hydrogels meeting the limitations of the acrylamide hydrogels of the claims. In support of this, Applicants attach the following Declaration Under 37 C.F.R. § 1.132 by Robert Lessél ("Lessél Declaration"). At paragraph 10, Mr. Lessél relates that the hydrogel products of Examples 1-3 of Pavlyk were analyzed and found to contain mean amounts of residual monomeric acrylamide of 1278 ppm, 2646 ppm and 693 ppm, respectively, values well above the 50 ppm limit for the hydrogels of the claimed methods. The laboratory data obtained from the analysis is presented in Appendix 1 of the Declaration. The data in Appendix 1 also provides factual evidence that the reaction between the acrylamide and the methylene bis-acrylamide does not go to completion, contrary to the Examiner's contention. Thus, Pavlyk cannot be used to render the 50 ppm element of Applicants' claims obvious.

The Examiner also contends that it is known in the art that urinary incontinence is treated by administering a prosthetic device comprising polyacrylamide hydrogel into the urethra, according to Annis. (Office Action, at page 6, lines 5-6.) The Examiner states that the "Annis art specifically teaches that acrylamide hydrogels [are] administered to treat incontinence." (Office Action, at page 9, lines 12-13.)

Applicants note that independent claims 111, 115, 116 and 117, as currently presented, recite that the hydrogel is administered *into* the urethra. Contrary to the Examiner's statements, Annis describes a solid prosthetic device designed to elevate the bladder from the pelvic floor, and is not administered *into* the urethra, but rather outside the urethra. Thus, Annis is unrelated to the use of polyacrylamide as a bulking agent and cannot be used to render Applicants' claims obvious.

The Examiner also contends that it is known, according to RU 2,148,957 (Sknar) and as admitted by Applicants, that the polyacrylamide hydrogel is injected into the ostium of the ureter to impede the flow of urine (Office Action, at page 6, lines 1-4), and later concludes that one having ordinary skill in the art would have been motivated to inject the acrylamide hydrogel into the ostium of the ureter or into the urethra "with the expectation that the hydrogel would act as a bulking material that would create increased resistance to the flow [of] urine in the urethra or the ureter that would lead to the treatment of urinary incontinence." (Office Action, at page 6, lines 9-13.)

Applicants submit that, contrary to the Examiner's assertions, one having ordinary skill in the art, in view of the cited references and, in particular, Sknar, would not have been motivated to use acrylamide hydrogel as a bulking agent to treat urinary incontinence. Moreover, one having ordinary skill in the art would not have reasonably expected success in using polyacrylamide as a bulking agent to treat urinary incontinence. To support this, Applicants attach the following Declarations Under 37 C.F.R. § 1.132 by Ieva Ankorina-Stark ("Ankorina-Stark Declaration") and David Diamond ("Diamond Declaration").

The enclosed Declaration by Dr. Ankorina-Stark evidences that, at the time of filing of the current application, there was a general bias against use of polyacrylamide as a prosthesis. (Ankorina-Stark Declaration, ¶ 8.) The safety of polyacrylamide in general was doubted, and these doubts were not yet ascribed to the residual monomer content. (Ankorina-Stark Declaration, ¶¶ 9-10.) Moreover, the general thinking in the field at the time was that

polyacrylamides outside the solid weight content range of 3.5-9%, as in Pavlyk, did not have the appropriate viscosity to serve as prosthetic devices. (Ankorina-Stark Declaration, ¶ 16.) The Ankorina-Stark Declaration thus evidences that the present invention was in contradistinction to the general school of thought of the time.

The enclosed Declaration by Dr. Diamond also evidences that a person skilled in the art would not have expected from the teachings of Sknar that the Pavlyk hydrogels or polyacrylamide hydrogels would be suitable for treating urinary incontinence, based on the medical and physiological differences between urinary incontinence and vesicoureteric reflux, as well as on differences in the material requirements for bulking agents in treating these two very different medical conditions. (Diamond Declaration, ¶¶ 6-8.)

Thus, Applicants submit that one of skill in the art, in view of Pavlyk, RU 2148957 (Sknar), Annis, and Applicants' admission, would not have arrived at Applicants' methods of treating urinary incontinence as presently claimed. As discussed above, one of skill in the art would not have been motivated to use acrylamide hydrogel as a bulking agent to treat urinary incontinence, and would not have reasonably expected success in using polyacrylamide as a bulking agent to treat urinary incontinence, in light of the cited references.

Moreover, the cited references, alone or in combination, fail to teach all the elements of the methods as presently claimed. In particular, as discussed above, Pavlyk fails to disclose polyacrylamide hydrogels meeting all the limitations of the acrylamide hydrogels of the claims, as shown in the enclosed Lessél Declaration, which clearly indicates that the Pavlyk hydrogels had high levels of monomeric acrylamide units, well above the 50 ppm limit recited in the present claims (Lessél Declaration, ¶ 10 and Appendix 1). RU 2148957 (Sknar), Annis, and Applicants' admission, fail to remedy the deficiencies of Pavlyk or to provide hydrogels meeting all the elements of those recited in the presently claimed methods.

According, Applicants submit that the claimed methods would not have been obvious in light of the cited references.

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 also stand rejected as allegedly being unpatentable over Vogel *et al.*, U.S. Pat. No. 6,335,028 ("Vogel") in view of RU 2148957 and Applicants' admission (in Applicants' February 23, 2006 interview at the US PTO, and in Applicants' remarks filed on February 27, 2006), and further in view of

Annis *et al.*, U.S. Pat. No. 4,857,041 ("Annis"). (Office Action, at page 9, lines 16-19, paragraph 7.)

Specifically, the Examiner asserts that one having ordinary skill in the art would have been motivated to administer the hydrogel of Vogel as a prosthetic device according to the teachings of Annis, Sknar, or Applicant's admitted prior art, with the expectation of bulking the urethra to treat urinary incontinence or impede urine flow. (Office Action, at page 11, lines 2-5.) The Examiner further notes that claim 9 and its dependent claims "do not inject the hydrogel into the urethra." (Office Action, at page 12, lines 12-13.)

Vogel related to a type of combination gel comprising a suspension of microspheres, a material very different from the hydrogel recited in the claimed methods. As discussed above, Annis describes a solid prosthetic device designed to elevate the bladder from the pelvic floor, which is not administered *into* the urethra, but rather outside the urethra. Moreover, the enclosed Declaration by Dr. Diamond evidences that a person skilled in the art would not have presumed or reasonably expected that a given demonstration of using a bulking agent to correct vesicoureteric reflux, as in Sknar, would be predictive of success in treating urinary incontinence with that bulking agent. (Diamond Declaration, ¶ 8.)

Applicants thus submit that one having ordinary skill in the art would not have been motivated to administer the hydrogel of Vogel as a prosthetic device according to the teachings of the recited references, with the expectation of bulking the urethra to treat urinary incontinence or impede urine flow, and thus arrive at Applicants' methods of treating urinary incontinence as presently claimed. Accordingly, Applicants believe that the claimed methods would not have been obvious in light of Vogel, Annis, Sknar, or Applicant's alleged admissions.

Applicants believe that the rejections of claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 under 35 U.S.C. § 103 have been overcome and respectfully request that the Examiner withdraw these rejections.

IV. The Provisional Double Patenting Rejection

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being

unpatentable over claims 1, 10-14, 16-18, and 20-42 of co-pending Appl. No. 11/469,213. (Office Action, at page 13, lines 6-8.)

Applicants request that the obviousness-type double patenting rejection be held in abeyance until all remaining rejections and objections have been withdrawn and there is an indication of allowable subject matter.

CONCLUSION

Based on the foregoing, Applicants respectfully request that the Examiner reconsider all rejections and that they be withdrawn. Applicants believe that the application is in condition for allowance, and they solicit an early indication to this effect. Examiner Fubara is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

Date June 11, 2008 By S. A. Bent

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